JUN 13 2012

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RENOVIS Surgical Technologies, Inc. **510(k)# K112897**

510(k) Summary

Submitter's Name: Renovis Surgical Technologies, Inc.

Address: 1901 W. Lugonia Ave, Ste 340
Redlands, CA 92374

Contact Person: **Anthony DeBenedictis**
Vice President of Quality Assurance
Phone: 909.557.2360

Date Prepared: May 31, 2012

Classification Name:	Prosthesis, Hip Revision System
Common Name:	Surgical Hip Joint Replacement System
Model Number:	A400
Product Code:	OQG, OQI, LPH, LZO
C.F.R. Section:	888.3353-Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. 888.3358-Hip joint metal/polymer/ metal semi-constrained porous-coated uncemented prosthesis.
Recommended Classification:	Class II
Classification Panel:	Orthopedics
Reason for Submission:	Traditional 510(k)

Device Description:

The Renovis Surgical Technologies, Inc. A400 Surgical Hip Replacement System (Renovis A400 Hip System) is a family of components designed in a variety of standard clinically usable sizes for cementless total hip replacements (i.e. replacements where both the femur and acetabulum are replaced).

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The system consists of four main components available in a variety of clinically usable sizes.
A) Femoral Stem (titanium alloy)
B) Femoral Head (CoCr and Biolox delta ceramic)
C) Acetabular Cup (titanium alloy)
D) Acetabular Liners (Mechanically annealed HXL polyethylene with and without alpha-tocopherol)

The Renovis A400 Hip System implant components are provided sterile and are for single use.

Indications for Use

The Renovis A400 Surgical Hip Replacement System is indicated for patients suffering from:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and
5. Revision procedures where other treatment or devices have failed.

The Renovis A400 Surgical Hip Joint Replacement Prosthesis is intended for cementless applications.

Predicate Devices

Predicate List

510(k) Number	Manufacturer
K030055	Biomet Manufacturing
K032396	Biomet Manufacturing
K051411	Biomet Manufacturing
K061312	Biomet Manufacturing
K070364	Biomet Manufacturing
K073102	Biomet Manufacturing

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K091956	DJO Surgical
K094035	StelKast, Inc.
K043537	Biomet Manufacturing
K093235	Biomet Manufacturing
K981211	Sulzer Orthopedics

Substantial Equivalence

The Renovis A400 Surgical Hip Replacement System claims substantial equivalence to commercially available hip prosthesis systems and related hip system components manufactured by Biomet Manufacturing Corporation (Biomet).
The Renovis A400 Hip System's intended use and indications for use are identical to the Biomet hip prosthesis system and associated components.

The Renovis A400 Hip System implanted components: femoral stem; femoral head; acetabular cup; acetabular liners, with vitamin E and without vitamin E are equivalent and raise no new question of safety or technology to those devices manufactured by Biomet. The materials used for all Renovis A400 Hip System components are similar to those used in the components of the Biomet hip prosthesis system predicate devices. All materials used in the Renovis A400 Surgical Hip Replacement System are biocompatible and are well known and commonly used in the orthopedic implant industry.

Performance Testing

Comprehensive bench performance testing conducted on the hip system components: femoral stems, femoral heads, and acetabular liners demonstrated that the A400 Hip System design is safe for its intended use and is substantially equivalent to the predicate devices.
The following bench/ performance testing was conducted on the A400 Hip System:

A) A400 Hip System – The following device tests were performed on the complete A400 Hip system and demonstrate the system is safe for its intended uses and is substantially equivalent to the predicate devices:

1. Distal Stem Fatigue Testing per ISO 7206-4:2002/ Guidance for Industry and FDA Staff – Non-clinical Information for Femoral Stem Prostheses, September 1997
2. Proximal Stem Fatigue Testing per ISO 7206-6:1992/ Guidance for Industry and FDA Staff – Non-clinical Information for Femoral Stem Prostheses, September 1997
3. Push-out Snap-Lock Testing of Acetabular Liners and Shells per ASTM F1820-97

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4. Lever-out and Torque-out Snap-Lock Testing of Acetabular Liners and Shells
5. CoCr Head Attachment Testing per ISO 7206-10:2003
6. BIOLOX delta Ceramic Heads Attachment Testing per FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems
7. Range of Motion Analysis
8. Hip Simulator Wear Testing under Normal Conditions per ISO 14242-1
9. Hip Simulator Wear Testing under Abrasive Wear Conditions per ISO 14242-1
10. Wear Debris Characterization per ASTM F1877-05

B) Femoral Stem and Acetabular Cup Porous Surface/Coating- the following tests were performed to evaluate the integrity of the porous surface/coating:

1. Abrasion resistance per ASTM F1978
2. Shear fatigue strength per ASTM F1160
3. Static shear strength per ASTM F1044
4. Static tensile strength per ASTM F1147
5. Characterization per ASTM F1854

C) Acetabular Liner – The following poly characterization testing, both chemical and mechanical, was performed on the HXL polyethylene materials:

1. Heat of fusion , melting point, and percent crystallinity per ASTM F2625/D3418
2. Small punch test properties (peak load, ultimate load, ultimate displacement, work to failure) per ASTM F2183
3. Oxidation measurement per ASTM F2102
4. Trans-vinylene yield per ASTM F2381
5. Crosslink density (Swell Ratio Testing) per ASTM F2214
6. Tensile properties (yield strength, ultimate strength, elongation at break, elastic modulus) per ASTM D638
7. Izod impact strength per ASTM D256 /F648
8. GCMS and LCMS extract analyses
9. Vitamin E content
10. Fatigue crack propagation per ASTM E647
11. Compressive modulus per ASTM D695
12. Uniformity of radiation dose
13. Free radical content (Electron Spin Resonance)
14. Consolidation verification
15. Density per ASTM D1505/D792

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All poly characterization test results demonstrate that the A400 Hip System design is safe for its intended use and is substantially equivalent to the predicate devices.

D) Polyethylene Biocompatibility – The following tests in accordance with ISO 10993 (permanent implant panel) were performed on the polyethylene material to demonstrate biocompatibility:

1. Systemic Toxicity: Materials Mediated Rabbit Pyrogen Test per ISO 10993-11 and -12
2. Systemic Toxicity: Acute Systemic Toxicity per ISO 10993-11 and -12
3. In Vitro Cytotoxicity Study Using the ISO Elution Method per ISO 10993-5
4. Genotoxicity: Chromosomal Aberration per ISO 10993-1, -3,-5, and -12.
5. Genotoxicity: In-Vivo Mouse Micronucleus Assay per ISO 10993-3 and -12
6. Genotoxicity: Bacterial Reverse Mutation per ISO 10993-3.
7. Irritation and Skin Sensitization: Intracutaneous Study per ISO 10993-2 and -10.
8. ISO Muscle Implantation Study in Rabbits– 2 Weeks per ISO 10993-2 and -6
9. ISO Muscle Implantation Study in Rabbits– 13 Weeks per ISO 10993-2 and -6
10. Irritation and Skin Sensitization: Guinea Pig Maximization Sensitization Test per ISO 10993-2 and -10
11. Systemic Toxicity: Sub-Chronic (14 Day) Intravenous Toxicity Study per ISO 10993-11 and -12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 13 2012

Renovis Surgical Technologies, LLC
c/o David Teicher, DuVal & Associates
825 Nicollet Mall
Minneapolis, Minnesota 55402

Re: K112897
Trade/Device Name: Renovis A400 Hip Joint Replacement Prosthesis
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: OQG, OQI, LPH, LZO
Dated: May 4, 2012
Received: May 7, 2012

Dear Mr. Teicher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

RENOVIS Surgical Technologies, Inc. K112897

Indications for Use

510(k) Number (if known): K112897

Device Name: Renovis A400 Surgical Hip Joint Replacement Prosthesis

Indications for Use:

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Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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